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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,308	06/01/2001	Kyogo Itoh	0020-4872P	3463
2292	7590	06/01/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,308	ITOH ET AL.9	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12, 15-17, 19, 20, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12, 15, 17, 19, 20, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>05062004</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

SUPPLEMENTAL DETAILED ACTION

RE: Itoh *et al*

Priority Date: 30 November 1999

1. The amendment filed 2/4/2004 is acknowledged and entered into the record. Accordingly, claims 1-6, 13-14, 18, and 21-27 are canceled without prejudice or disclaimer.
2. Claims 7-12, 15-17, 19-20, and 28-29 are pending.
3. Claim 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10/02/2002.

It is noted that the applicant traverses the withdrawal of claim 16 and states that the claim is drawn to derivatives of one of SEQ ID No: 3-5, of which were examined on the merits. Applicant's traversal is noted, however, applicant elected in a paper filed 5/15/2003 to pursue the sequence of SEQ ID No: 5 as the initial species for examination and therefore only claims that read on SEQ ID No: 5 were examined on the merits. All other sequences which did not read on the elected species were withdrawn from further consideration as being drawn to a non-elected species. Furthermore, because art was applied to the elected species (SEQ ID No: 5), an examination of other species found within the Markush group were not searched (i.e. SEQ ID No: 3-4), nor were any other sequence. The restriction is thereby held proper and was made FINAL in the last office action.

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4. Claims 7-12, 15, 17, 19-20, and 28-29 are examined on the merits.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

6. The Information Disclosure Statement filed 6/1/2001 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

7. The rejection of claims 9-12, 15, 17, 19-20, and 28-29 under 35 USC 112, 1st paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that the written description for tumor antigen peptides is defined as those "peptides of 8-14 amino acids in length" and "derivatives" are defined by the substitutions at amino acid position 2 and/or the C-terminus by any amino acid so long as the "derivative" is "functional equivalent". This argument is not deemed persuasive to overcome the rejection of record because the specification has not defined the intended amino acid sequences. Furthermore, the substitution of any amino acid into the derivative has not been defined nor has a specific functional correlation been provided so that one of skill in the art would know that the applicant was in possession of a representative number of derivatives that are functionally equivalent.
8. Applicant further argues that selection of specific amino acid sequences represented by sequence identification numbers have been exemplified in the specification,

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however, because the currently amended claims recite "fragments of SEQ ID No: 1" and because the SEQ ID Nos: 3-5 are not all encompassing of all the possible fragments claimed and because there are no functional characteristics associated with the desired fragments, one of skill in the art cannot specifically recognize that the species of fragments claimed is representative of the broad genus of any and all fragments of SEQ ID No: 1. The fragments represented by SEQ ID No: 3-5 do not have a core sequences which can be specifically correlated or predictable so as to be representative of the broad class of fragments claimed. Therefore, the rejection under 35 USC 112, 1st paragraph as lacking written description is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

9. The rejection of claims 9, 11-12, 15 and now newly rejected claim 10 under 35 USC 102(b) as being anticipated by Nagase *et al* is maintained for the reasons of record. Applicant argues that the prior art fails to anticipate the claims as currently amended because Nagase *et al* fail to teach a peptide that is 8-14 amino acids in length and fails to teach function or activity of the claimed peptide. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Because the claims are interpreted as being open, Nagase *et al* still anticipates the peptide of the claimed invention. The claims are drawn to a peptide of 8-14 amino acids in length that is comprised within SEQ ID No: 1. Because the Nagase *et al* teach a protein that is 100% identical to that of SEQ ID No: 1, any peptide fragment of SEQ ID No: 1 would be anticipated. Further applicant argues that the function and

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activity of the peptide is not disclosed by Nagase *et al.* Because the invention is drawn to the product *per se*, the function and activity of the peptide would be an inherent property and would not be a patentable distinction from the peptide taught by Nagase *et al.* Lastly, applicant argues that amended claim 12 is not anticipated because Nagase *et al.* do not teach the characterization of a peptide that is identical to SEQ ID No: 5, nor does Nagase *et al.* recognize the function of the small peptide of 8 amino acids.

Although the small 8 amino acid sequence is not recognized by Nagase *et al.* as an independent fragment, the claims as currently amended do not preclude sequences found endogenously in SEQ ID No: 1, because the invention is claimed broadly and encompasses the entire sequence taught by Nagase *et al.*

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

10. The rejection of claims 7-8, 17, and 20 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that at the time the invention was made others were able to demonstrate successful usage of tumor antigen peptides *in vivo*. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The references provided do not provide any indication nor do they provide any correlation between the tumor antigen peptides taught in those references to the peptides claimed in the instant specification. One of skill in the art cannot reasonably extrapolate the findings in those references to the instant invention because those references do not shed any light on the ability of the instant peptide to work *in vivo* as a pharmaceutical

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composition. The extrapolation of knowledge from the prior art and from the instant specification would not provide the skill artisan with enough guidance to use the composition in the form of a pharmaceutical composition because the effectiveness of the composition cannot be readily anticipated as functional in the absence of a working example in vivo. One of skill in the art would not be able to predict with any certainty that the peptides of the instant invention would act in a manner similar to those taught in the prior art references cited. Therefore the rejection under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record.

New Arguments

Claim Rejections - 35 USC § 112, 2nd paragraph

11. Claims 7-8, 17, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims that read on "pharmaceutical" compositions, it is unclear as to what other component is intended in the "composition". A composition is defined a substance that comprises more than one component (see Merriam-Webster Online wherein a "composition" is defined as a "product of mixing or combining various elements or ingredients").

Claim Rejections - 35 USC § 112, 1st paragraph

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12. Claims 7-8, and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 7-8 and 28 recite specific cell lines.

It is apparent that the recited cell lines are required to practice the claimed invention, because they are specifically required in the claims. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the cell lines listed in claim 7. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cell lines of claims 7-8 and 28, and they do not appear to be readily available material. Deposit of the cell lines would satisfy the enablement requirements of 35 U.S.C. 112. While the specification states on page 11 that the cell lines have been deposited at The National Institute of Bioscience and Human Technology, the specification does not indicate the terms of the deposit.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public

of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
 - (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
 - (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
 - (d) a viability statement in accordance with the provisions of 37 CFR 1.807;
- and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 2/4/2004.

Conclusion

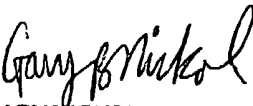
14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
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GARY NICKOL
PRIMARY EXAMINER

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April 28, 2004